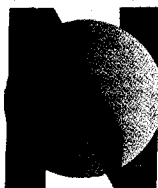


9-25



LIPID NURSE TASK FORCE MANAGING CARDIOVASCULAR DISEASE

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Presented by Suzanne Hughes RN BSN

June 29, 2000

9:30 a.m.

Representing the Preventive Cardiovascular Nurses Association
(formerly the Lipid Nurse Task Force)

To: The Food and Drug Administration
Regarding: Over the Counter Drug Products Public Hearing
Docket No. 00N-1256

To whom it may concern:

The Preventive Cardiovascular Nurses Association (PCNA), formerly the Lipid Nurse Task Force, is a national organization of professional nurses dedicated to the primary and secondary prevention of coronary artery disease, vascular disease, and stroke. Our mission is achieved through professional and public education, through increasing consumer awareness of the importance of cardiovascular risk reduction and through advocacy of the need for nursing involvement in the care of persons and families at risk for coronary disease and stroke.

It is estimated that 98 million Americans have blood cholesterol levels of 200 mg./dL and over. This number represents 52% of our adult population. In numerous well-designed clinical trials over the past ten years involving hundreds and thousands of American adults, cholesterol lowering, through use of HMG-CoA reductase inhibitors, has been found to be remarkably safe and effective. The results of these trials demonstrated substantial reductions in morbidity as well as mortality. The benefit to quality of life and to the reduction in cost of hospitalizations for coronary disease and stroke is also enormous. These benefits are seen across the adult age span as well as across genders. What is also clear is that millions of Americans with modestly elevated cholesterol are not being identified and/or treated adequately. The need for an effective treatment for elevated cholesterol and the availability of this very safe and effective medication compels us to seriously consider the great public health benefit of allowing this class of medications to be made available over the counter.

We strongly support the concept of OTC availability of an HMG-CoA reductase inhibitor based upon the satisfaction of the following criteria:

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1. That research demonstrates that the population who chooses to use the product is comprised of appropriate candidates for OTC lipid-lowering therapy, with regard to age, medical history, and baseline lipid levels.
2. That research shows that those who elect to use the product follow the instructions on the label with regard to dosage and frequency.
3. That research shows that those who elect to use the product communicate with their healthcare providers regarding its use and for clinical follow-up.

The board of directors of the PCNA strongly recommend that the FDA consider the benefits of bringing HMG-CoA reductase inhibitors over the counter in order to reduce the burden of cardiovascular disease and stroke that affects one in two adult Americans.

Respectfully submitted,

Kathy Berra MSN ANP
Suzanne Hughes RN BSN
For the Board of Directors of the Preventive Cardiovascular Nurses
Association